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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,055	09/25/2006	Susanne Busch	2923-779	8810
6449 7590 03/02/2011 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005				
EXAMINER MAEWALL, SNIGDEHA				
ART UNIT 1612		PAPER NUMBER		
NOTIFICATION DATE 03/02/2011		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/594,055

Applicant(s)

BUSCH ET AL.

Examiner

Snigdha Maewall

Art Unit

1612

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-34, 36-49, 51 and 52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-34, 36-49 and 51-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Summary

1. Receipt of IDS filed on 09/25/06 is acknowledged.

Claims 1-28, 35 and 50 have been cancelled.

Claims 53 -54 have been withdrawn. Claims 55-56 remain withdrawn as being drawn to non-elected subject matter.

Accordingly, claims **29-34, 36-49 and 51-52** are under prosecution.

New rejections are necessitated by claim amendments.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims **29-34, 36-49 and 51-52** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 29 recites the limitation alkaline medium which makes the claim indefinite. The metes and bounds of alkaline medium in claim 29 is not clear, it is not clear whether the alkaline medium is solution or alkaline gel in claim 29 subsection a. If it is solution then the subsection d reads on subsection a of claim 29. Claim 56 defines process of growth of apatite, the time frame for the treatment is not defined in claims, absent indication of for how long or how much amount is treated with for various ingredients, and the claim is ambiguous.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 29-34, 36-38, 48- 49 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raaf et al. (US 4,397,837) in view of DiGiulio et al. (USP 4,080,440).

Raaf et al. disclose two-part compositions, one comprising a soluble **calcium** and the second comprising a **soluble phosphate**. The compositions are for the remineralization or inhibiting demineralization of teeth. Demineralization is when the apatite crystals are degraded (col. 1, lines 27-28). Therefore it appears the compositions form apatite crystals on the teeth. Each part is added to the teeth in **sequential order**. The compositions may be in the form of a paste, a **gel**, or a **solution**

(col. 2, lines 43-44). The gels include known thickeners (col. 4, line 13). An example of a thickener used in the compositions is carboxymethylcelluloses and caragheenate (see examples). The compositions also comprise glycerol (see examples). The compositions also comprise fluoride in the phosphate comprising part and comprise no fluoride in the calcium containing part. **Gelatin** was used in the compositions disclosed by the examples and is a thickening agent¹. **Another embodiment of the inventions is to provide more than two layers wherein the third layer optionally comprises a fluoride component (col. 6, lines 3-10).** It is concluded that the layer may be free of fluoride. The phosphate and calcium phases are separated during storage containers such as two-component tubes and can be kept separate and dispensed separately from one another. Since the reference teaches more than two layers, one of ordinary would envisage applying layer with only gel layer. The pH of the alkaline medium is although not disclosed in the reference, however, it can be inferred that the medium comprising calcium will be considered to possess the claimed pH which is from 6 to 8 because of calcium ions which are basic in nature absent evidence to contrary. Absent indication of specific medium in claim 29 under subsection a, the calcium ions will read on subsection d. The reference does not disclose the multi-part compositions are gels with one gel comprising phosphate ions, a second gel medium comprising calcium ions but the compositions may be in the form of gels. Therefore, one of ordinary would envisage formulating compositions with one part with phosphate ions and second part with calcium ions and since in one of the embodiments, the reference discloses that more

¹ Gaffar et al. (US 4,474,750) col. 5, lines 10-21).

than two layers can be applied, one of ordinary would envisage applying another layer with or without phosphate and calcium in order to prolong application due to gel characteristics.

Raaf et al. discloses calcium ions containing medium which can be interpreted as an alkaline medium since it has alkali salt in it, however, specific mention of alkaline medium is missing from the reference.

DiGiulio et al. discloses that use of slightly alkaline supersaturated calcium phosphate solutions effect some degree of enamel remineralization, see column 1, lines 45-48. Example 1 teaches utilizing alkaline NaOH 10 % solution in tooth paste preparation in column 8. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate an alkaline medium comprising calcium ions into the apatite forming composition of Raaf et al. in order to effect better and effective remineralization that is apatite formation. The solution containing calcium ions claimed under subsection d, reads on subsection a as recited because no specific medium has been defined in subsection a. additionally, repetition of step of subsection a, would be obvious absent indication of unexpected results. Absent indication of contact time or specific medium in subsection a (whether solution or gel) and absent indication of specific calcium and phosphate ions which provide unexpected results, prior art's generic disclosure for applying gel or solution comprising calcium and phosphate ions would be obvious from the teachings of prior art.

7. Claims 38 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raaf et al. (US 4,397,837) in view of DiGiulio et al. (USP 4,080,440) and further in view of Wiedemann (US 6,010,684).

The references discussed above do not disclose the pH of the compositions.

Wiedemann discloses two part compositions comprising in one-part phosphate ions and in the second calcium ions for the remineralization of teeth (col. 1, lines 11-20). The phosphate compositions have a pH of 3.0 to 6.5 and the calcium compositions have a pH from 3.0 to 7.0 encompassing claims 38 and 51. The compositions may also comprise fluoride ions in the phosphate comprising composition. The resulting mixture should yield a pH from 2.0 to 5.0 (col. 1, lines 59-67). The pH remineralization of the teeth is dependent on the pH of the compositions and results in a deep remineralization effect.

It would have been obvious to one of ordinary skill in the art to have adjusted the pH of each gel of the primary reference motivated by the desire to obtain the deep remineralization effects when the phosphate is reacted with calcium as disclosed by the secondary reference.

8. Claims 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raaf et al. (US 4,397,837) in view of DiGiulio et al. (USP 4,080,440) and further in view of Barth et al. (US PG pub. 20070154411).

Raaf et al. and DiGiulio et al. as discussed above do not disclose fluoroapatite or particle size.

Barth et al. teaches utilization of fluoroapatite, hydroxyapatite, calcium hydrogen phosphate and calcium fluoride as remineralization –promoting agent and the amount to be added in the composition is from 0.1 to 10% by weight, see [0062] and [0061]. The particle size is disclosed to be from 1 to 200 microns in [0042].

It would have been obvious to one of ordinary skill in the art to have utilized the remineralization –promoting components such as fluoroapatite in the compositions of Raaf et al. for promoting better remineralization because Raaf teaches utilization of calcium salts for apatite formation and '411 teaches the specific calcium salts for the same cause that is dental remineralization. Optimization of particle would be obvious to one of ordinary skill in the art in order to achieve optimum results absent evidence of unexpected results with the claimed sizes.

9. Claims 29-34, 36-38, 48- 49 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebner (DE 33 03 937 Translation) in view of Singh et al. (US 2003/0152528) and further in view of DiGiulio et al. USP 4,080,440.

Ebner discloses **gel** compositions comprising **phosphate** gelatinized solutions and **calcium** gelatinized solutions. The method includes applying a phosphate salt to the teeth with a cap followed by the application of a calcium salt with a cap or vice versa. **Gelatin** is used as the gelatinizing agent. A fluoride source is also incorporated into the phosphate compositions, (thus reads on fluoride in first gel). Additional agents such as anti-bacterial agents and whitening agents may also be included in one of the caps (page 7). The solution containing calcium ions claimed under subsection d, reads on subsection a as recited because no specific medium has been defined in subsection

a. additionally, repetition of step of subsection a, would be obvious absent indication of unexpected results. The solution of calcium will be interpreted to be from 6 to 8 due to calcium solution being an alkaline medium.

The reference does not disclose a second gel that is absent of phosphate or fluoride ions.

Singh et al. disclose hydrogel compositions for whitening teeth. The reference is used as a general teaching to show active ingredients may be separated into different layers depending on their reactivity to one another. The hydrogels may have one or more additional hydrogel or non-hydrogel layers comprising additives that are not compatible with the whitening agent (paragraph 0116).

It would have been obvious to one of ordinary skill in the art to have used a three gel system in forming the calcium phosphate layer on the teeth disclosed by the primary reference motivated by the desire to inhibit the phosphate or calcium ion from possibly reacting with additional additives as disclosed by the secondary reference.

The references discussed above disclose calcium ions containing medium which can be interpreted as an alkaline medium since it has calcium salt in it, however, specific mention of alkaline medium is missing from the reference.

DiGiulio et al. discloses that the use of slightly alkaline supersaturated calcium phosphate solutions effect some degree of enamel remineralization, see column 1, lines 45-48. Example 1 teaches utilizing alkaline NaOH 10 % solution in tooth paste preparation in column 8.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate an alkaline medium comprising calcium ions into the apatite forming composition of Ebner et al. in order to effect better and effective remineralization that is apatite formation.

10. Claims 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebner (DE 33 03 937 Translation) in view of Singh et al. (US 2003/0152528), DiGiulio et al. USP 4,080,440 as discussed above and further in view of Barth et al. (US PG pub. 20070154411).

The references discussed above do not disclose fluoroapatite or particle size. Barth et al. teaches utilization of fluoroapatite, hydroxyapatite, calcium hydrogen phosphate and calcium fluoride as remineralization –promoting agent and the amount to be added in the composition is from 0.1 to 10% by weight, see [0062] and [0061]. The particle size is disclosed to be from 1 to 200 microns in [0042].

It would have been obvious to one of ordinary skill in the art to have utilized the remineralization –promoting components such as fluoroapatite in the compositions of Raaf et al. and references discussed above for promoting better remineralization because Raaf teaches utilization of calcium salts for apatite formation and '411 teaches the specific calcium salts for the same cause that is dental remineralization. Optimization of particle would be obvious too ne of ordinary skill in the art in order to achieve optimum results absent evidence of unexpected results with the claimed sizes.

11. Claims 38 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebner (DE 33 03 937 Translation) in view of Singh et al. (US 2003/0152528), DiGiulio et al. USP 4,080,440 as discussed above and further in view of Wiedemann (US 6,010,684).

The references discussed above do not disclose the pH of the compositions.

Wiedemann discloses two part compositions comprising in one-part phosphate ions and in the second calcium ions for the remineralization of teeth (col. 1, lines 11-20). The phosphate compositions have a pH of 3.0 to 6.5 and the calcium compositions have a pH from 3.0 to 7.0 encompassing claims 38 and 51. The compositions may also comprise fluoride ions in the phosphate comprising composition. The resulting mixture should yield a pH from 2.0 to 5.0 (col. 1, lines 59-67). The pH remineralization of the teeth is dependent on the pH of the compositions and results in a deep remineralization effect.

It would have been obvious to one of ordinary skill in the art to have adjusted the pH of each gel of the references discussed above motivated by the desire to obtain the deep remineralization effects when the phosphate is reacted with calcium as disclosed by the secondary reference.

Response to Arguments

12. Applicant's arguments filed 12/20/10 have been fully considered but they are not persuasive.

Applicant argues that both Raaf and DiGuilio are directed to two-component, single-phase systems, whereas the presently claimed composition is distinguished from the cited art because it is a multi-component, multi-phase system, requiring an alkaline medium comprising calcium ions, a first gel comprising gelatin and phosphate ions, a second gel, which is free of phosphate ions and calcium ions, capable of covering a first layer of said first gel with a layer of the second gel, and a solution containing calcium ions. Accordingly, Applicants submit that because independent claim 29 is not anticipated by Raaf for the reasons stated above, and because DiGuilio does not remedy the deficiencies of Raaf, claims 30-34, depending from claim 29 are not rendered obvious by the combination of Raaf and DiGuilio.

These arguments are not persuasive because in one of the embodiments, Raaf teaches that the invention provides more than two layers wherein the third layer optionally comprises a fluoride component (col. 6, lines 3-10). Since the reference teaches more than two layers, one of ordinary would envisage applying layer with only gel layer. The pH of the alkaline medium is although not disclosed in the reference, however, it can be inferred that the medium comprising calcium will be considered to possess the claimed pH which is from 6 to 8 because of calcium ions which are basic in nature absent evidence to contrary. Absent indication of specific medium in claim 29 under subsection a, the calcium ions will read on subsection d. The reference does not disclose the multi-part compositions are gels with one gel comprising phosphate ions, a second gel medium comprising calcium ions but the compositions may be in the form of

gels. Therefore, one of ordinary would envisage formulating compositions with one part with phosphate ions and second part with calcium ions and since in one of the embodiments, the reference discloses that more than two layers can be applied, one of ordinary would envisage applying another layer with or without phosphate and calcium in order to prolong application due to gel characteristics. Additionally, DiGiulio teaches use of 10% NaOH so as discussed above, one of ordinary would envisage modifying pH based on DiGiulio's reference. Applicant's arguments that DiGiulio teaches less than about 5 pH is not persuasive because a reference is considered as a whole and is not limited to only preferred embodiments.

Applicants argue that Wiedemann does not disclose multiphase system; therefore the reference does not disclose the claimed invention. These arguments' are not persuasive, as discussed earlier the Weidman's reference has been cited for pH limitations in calcium containing dental formulation.

Applicant argues regarding Ebner, Singh and DiGiulio that Ebner discloses placing caps containing a phosphate solution on teeth for some time and then placing a cap containing calcium solution on teeth. Thus, Ebner discloses applying the solutions to teeth separately, i.e., not as a composition or layer structure, but as separate solutions. The combination of Singh, DiGiulio, and Ebner would not have made it obvious to one of ordinary skill to produce the presently claimed composition because the cited references do not consider the biomimetic principles of the present invention, namely 1) an alkaline medium for pretreatment, 2) locally separated reactive ions in a bio-organic gel, 3) exclusion of external

stress/disturbances, and 4) mineralization conditions that bring about the formation of tooth enamel-like substances.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that is the biomimetic principles as discussed above) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants arguments that Ebner does not describe layered structure is without any basis because the instant claims recite the second gel capable of covering a first layer of said first gel with a layer of the second gel, therefore the claims do not recite layered structure, claims only recite composition comprising solution and gels.

Applicant argues that is unclear how one of ordinary skill would go about combining the disclosures of Ebner, DiGiulio, and Singh to arrive at a useful product. The metastable aqueous solution of DiGiulio, comprising both phosphate and calcium ions is contrary to the system of Ebner, which requires keeping the calcium and phosphate ions separated until after application and incubation for some time on teeth. One could imagine using the separate gelatin layers containing whitening and other active ingredients of Singh in one or both of the caps of Ebner, or perhaps using the separate application by caps method of Ebner to apply the composite active layers of Singh for teeth whitening, or even mixing up calcium and phosphate ions in each gel,

based on Singh, or each cap, according to Ebner, 5 minutes before application as suggest by DiGiulio.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case it is obvious as discussed above that secondary reference teaches the use of slightly alkaline supersaturated calcium phosphate solutions, effects some degree of enamel remineralization,(see column 1, lines 45-48. Example 1 teaches utilizing alkaline NaOH 10 % solution in tooth paste preparation in column 8., therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate an alkaline medium comprising calcium ions into the apatite forming composition of Ebner et al. in order to effect better and effective remineralization that is apatite formation.

Applicant further assert that It is clear that it is beyond mere routine or obvious modification to modify Ebner according to the disclosures of Singh and DiGiulio, taking individually, or in combination, to eliminate the two-phase, time-guided solution application process of Ebner and to instead somehow arrive at the presently claimed composition• Even a hypothetical picking and choosing of particular components and steps in an attempt to arrive at the presently claimed composition leads to a plethora of possibilities and difficulties. Thus, Applicants submit that the purported combination of

references is improper and unworkable because there is no clear and obvious way that the combination of the cited references would produce the presently claimed composition and that one of ordinary skill in the art, motivated by a desire to inhibit the phosphate or calcium ion from reacting with additional additives,

Applicants further submit that, even if one were to try to combine the disclosures of Ebner, Singh and DiGiulio, such a combination would still not render the present claims obvious. Ebner does not disclose using a second gel that is free of phosphate and calcium ions and Singh does not suggest incorporating such a layer. Rather, Singh discloses having a layer containing whitening active ingredient and additional layers containing other actives that are not compatible with the whitening agent. DiGiulio also does not remedy this deficiency. Thus, the combination is clearly deficient for this reason. Further, none of Ebner, Singh, or DiGiulio discloses an alkaline-calcium medium component used to pre treat as required by the present invention or the additional calcium solution component. While DiGiulio states that the prior art suggested using slightly alkaline calcium phosphate in a cap applied to roughened teeth for several days to effect some degree of remineralization (col. 1, lines 41-48), there is no suggestion to use an alkaline-calcium medium in the composition as a pre-treating component separate from, and in addition to, active and inactive gel components.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.

1986). As discussed earlier, Ebner generically teaches application of calcium ions, phosphate ions and use of gelatin. Singh teaches application of more than one layer to show active ingredients may be separated into different layers depending on their reactivity to one another and DiGiulio et al. discloses the use of slightly alkaline supersaturated calcium phosphate solutions effect some degree of enamel remineralization. Applicants piece meal analysis of various references does not overcome the obviousness rejections made above based on the combined teachings of prior art absent indication of unexpected results.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall
Art Unit 1612
/Gollamudi S Kishore /
Primary Examiner, Art Unit 1612